	Case 1:07-cv-09477-JFK Document 4-	10 Filed 11/09/2007 Page 1 of 18				
1 2 3 4 5 6 7	DOUGLAS C. EMHOFF (Cal. Bar No. 1) JEFFREY M. TANZER (Cal. Bar No. 1) 2049 Century Park East, Suite 2100 Los Angeles, California 90067 Telephone: (310) 229-9900 Facsimile: (310) 229-9901 E-mail: demhoff@venable.com E-mail: jtanzer@venable.com  Attorneys for Defendant MERCK & CO., INC.	151049) 29437) ES DISTRICT COURT				
9		RICT OF CALIFORNIA				
10	11 12	EASTERN DISTRICT OF CALIFORNIA				
9 11	ERNESTINE HIGHET,	CASE NO. 2:07-CV-01872-LKK-EFB				
2049 CENTURY PARK EAST, SUITE 2100 LOS ANGELES, CA 90067 310-229-9900 11	Plaintiff,	DEFENDANT MERCK & CO., INC.'S ANSWER TO COMPLAINT				
2049 CENTURY LOS AN	DOES 1 25 inclusive	DEMAND FOR JURY TRIAL				
17	Defendants.					
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21	Defendant, Merck & Co., Inc. ("Merck"), by and through its undersigned					
22	attorneys, hereby answers those allegations of Plaintiff's Complaint ("Complaint")					
23	directed to it. To the extent the allegations of any paragraph are directed at defe					
24	other than Merck, Merck is not required to respond to those allegations. To the extent a					
25	response is deemed necessary, Merck states that it denies all such allegations, except					
26	those that are specifically admitted below. Merck denies all allegations set forth in the					
27	Complaint directed at Merck except to the	e extent such allegations are specifically				
28	admitted below:  ANSWER TO COMPLAINT	1				

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#### I. JURISDICTION AND VENUE

- The allegations of the first sentence of Paragraph 1 are conclusions of law 1. to which no response is required. To the extent that a response is required, Merck denies each and every allegation of the first sentence of Paragraph 1. As to the allegations of the second sentence of Paragraph 1, Merck is without knowledge or information sufficient to form a belief as to these allegations, except that Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in New Jersey. As to the allegations in the third sentence of Paragraph 1, Merck admits for jurisdictional purposes only, that Plaintiff seeks in excess of \$75,000.
- The allegations of the first sentence of Paragraph 2 are conclusions of law 2. to which no response is required. To the extent a response is required, Merck denies the allegations of Paragraph 2.
  - The allegations of Paragraph 3 do not require a response. 3.

#### II. PARTIES

- Merck is without knowledge or information sufficient to form a belief as to 4. the allegations of Paragraph 4.
- Merck denies each and every allegation of Paragraph 5, except admits that 5. it is a New Jersey corporation with is principal place of business in New Jersey.
- Merck admits that it is registered to do business in the States of California 6. and New York.
- Merck is without knowledge as to what is meant by the phrase "regularly 7. transacted," so the allegations in Paragraph 7 are denied.
- 8. Merck denies each and every allegation of Paragraph 8, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 8 inconsistent with that prescribing information and respectfully refers the Court to the Physician's Desk Reference ("PDR") for

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FOSAMAX® for its actual language and full text.

- Merck admits only that it distributed FOSAMAX® for prescription in 9. accordance with its approved prescribing information and denies any allegations in Paragraph 9 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 9.
- Merck is without knowledge as to what is meant by the phrase "substantial 10. revenue," so the allegations in Paragraph 10 are denied.
- Merck is without knowledge as to what is meant by "consequences," so the allegations in Paragraph 11 are denied.

#### III. SUMMARY OF THE CASE

- 12. Merck denies each and every allegation of Paragraph 12, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.
  - Merck denies each and every allegation of Paragraph 13. 13.
  - Merck denies each and every allegation of Paragraph 14. 14.
  - Merck denies each and every allegation of Paragraph 15. 15.
  - Merck denies each and every allegation of Paragraph 16. 16.

#### IV. FACTUAL BACKGROUND

- Merck denies each and every allegation of Paragraph 17, except that it 17. admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.
- Merck denies each and every allegation of Paragraph 18, except that 18. Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 18 inconsistent with that prescribing information.

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- 19. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 19 inconsistent with that prescribing information. Merck also refers the Court to the prescribing information for Aredia and Zometa, and denies any allegations in Paragraph 19 with respect to Aredia and Zometa inconsistent with that prescribing information.
- do not and that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 20 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck also refers the Court to the prescribing information for Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid, and denies any allegations in Paragraph 20 with respect to Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid inconsistent with that prescribing information. Merck denies the remaining allegations of Paragraph 20.
  - 21. Merck denies each and every allegation of Paragraph 21.
  - 22. Merck denies each and every allegation of Paragraph 22.
  - 23. Merck denies each and every allegation of Paragraph 23.
- 24. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 24.
  - 25. Merck denies each and every allegation of Paragraph 25.
  - 26. Merck denies each and every allegation of Paragraph 26.
  - 27. Merck denies each and every allegation of Paragraph 27.
  - 28. Merck denies each and every allegation of Paragraph 28.
- 29. Merck denies each and every allegation of Paragraph 29, except that Merck admits that the FDA drafted an "ODS Postmarketing Safety Review," but respectfully refers the Court to said document for its actual language and full text.

1	30.	Merck denies each and every allegation of Paragraph 30.
2	31.	Merck denies each and every allegation of Paragraph 31.
3	32.	Merck denies each and every allegation of Paragraph 32.
4	33.	Merck denies each and every allegation of Paragraph 33, except that
5	Merck adm	nits that Fosamax product sales in 2006 amounted to approximately \$3.13
6	billion.	
7	34.	Merck is without knowledge as to whether Plaintiff used FOSAMAX®.
8	Merck den	ies the remaining allegations in Paragraph 34.
9	35.	Merck denies each and every allegation of Paragraph 35.
10	36.	Merck is without knowledge as to whether Plaintiff was prescribed
11	FOSAMA	X®. Merck denies the remaining allegations in Paragraph 36.
12	37.	Merck denies each and every allegation of Paragraph 37.
13	38.	Merck is without knowledge or information sufficient to form a belief as to
14	the allegati	ons of Paragraph 38.
15	39.	Merck is without knowledge or information sufficient to form a belief as to
16	the allegati	ons of Paragraph 39.
17	40.	Merck denies each and every allegation of Paragraph 40.
18	41.	Merck denies each and every allegation of Paragraph 41.
19	42.	Merck is without knowledge or information sufficient to form a belief as to
20	the allegati	ons of Paragraph 42.
21	43.	Merck denies each and every allegation of Paragraph 43.
22	44.	Merck denies each and every allegation of Paragraph 44.
23	45.	Merck denies each and every allegation of Paragraph 45.
24		COUNTS
25		<b>COUNT I: NEGLIGENCE</b>
26	46.	Merck repleads its answers to Paragraphs 1 through and including 45, and
27	by this rafa	rence hereby incornorates the same herein in this naragraph, and makes the

d including 45, and ence hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth verbatim. ANSWER TO COMPLAINT

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ANSWER TO COMPLAINT

47. The alle	egations in Paragraph 47 are conclusions of law to which no
response is required:	to the extent that a response is deemed necessary, the allegations
are denied and Merc	k respectfully refers the Court to the relevant legal standard,
including any confli	et of law rules.

- Merck denies each and every allegation of Paragraph 48, including each 48. and every allegation contained in subparts (a) through (f).
  - Merck denies each and every allegation of Paragraph 49. 49.
  - Merck denies each and every allegation of Paragraph 50. 50.

#### **COUNT II: STRICT LIABILITY**

- Merck repleads its answers to Paragraphs 1 through and including 50, and 51. by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth verbatim.
- Merck denies each and every allegation of Paragraph 52, except that it 52. admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff alleges he consumed.
- Merck denies each and every allegation of Paragraph 53, except that it 53. admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff alleges he consumed.
- Merck is without knowledge or information sufficient to form a belief as to 54. the allegations of Paragraph 54.
  - Merck denies each and every allegation of Paragraph 55. 55.
  - Merck denies each and every allegation of Paragraph 56. 56.
  - Merck denies each and every allegation of Paragraph 57. 57.
  - 58. Merck denies each and every allegation of Paragraph 58.

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59.	Merck denies	each and	every allegation	of Paragraph 5	9.

- Merck denies each and every allegation of Paragraph 60. 60.
- Merck denies each and every allegation of Paragraph 61. 61.
- 62. Merck denies each and every allegation of Paragraph 62.

#### **COUNT III: BREACH OF EXPRESS WARRANTY**

- 63. Merck repleads its answers to Paragraphs 1 through and including 62, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.
- Merck denies each and every allegation of Paragraph 64, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.
  - Merck denies each and every allegation of Paragraph 65. 65.
  - Merck denies each and every allegation of Paragraph 66. 66
- 67. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 67.
  - Merck denies each and every allegation of Paragraph 68. 68.
  - Merck denies each and every allegation of Paragraph 69. 69.

#### **COUNT IV: BREACH OF IMPLIED WARRANTY**

- 70. Merck repleads its answers to Paragraphs 1 through and including 99, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth verbatim.
- Merck denies each and every allegation of Paragraph 71, except that 71. Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.
- Merck denies each and every allegation of Paragraph 72, and respectfully 72. refers the Court to the FDA-approved prescribing information for any and all

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representations contained therein. Merck further avers that FOSAMAX® is a
prescription medication approved by the FDA for prescription in accordance with its
approved prescribing information.

- Merck denies each and every allegation of Paragraph 73. 73.
- Merck lacks knowledge or information sufficient to form a belief as to the 74. truth or falsity of the allegations of Paragraph 74.
  - Merck denies each and every allegation of Paragraph 75. 75.
- Merck lacks knowledge or information sufficient to form a belief as to the 76. truth or falsity of the allegations of Paragraph 76.
- Merck lacks knowledge or information sufficient to form a belief as to the 77. truth or falsity of the allegations of Paragraph 77.
  - Merck denies each and every allegation of Paragraph 78. 78.
  - Merck denies each and every allegation of Paragraph 79. 79.

#### **COUNT V: FRAUDULENT MISREPRESENTATION**

- Merck repleads its answers to Paragraphs 1 through and including 79, and 80. by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth verbatim.
- Merck denies each and every allegation of Paragraph 81, including each 81. and every allegation contained in subparts (a) through (b).
  - Merck denies each and every allegation of Paragraph 82. 82.
  - Merck denies each and every allegation of Paragraph 83. 83.
  - Merck denies each and every allegation of Paragraph 84. 84.
  - Merck denies each and every allegation of Paragraph 85. 85.
  - Merck denies each and every allegation of Paragraph 86. 86.
  - Merck denies each and every allegation of Paragraph 87. 87.
  - Merck denies each and every allegation of Paragraph 88. 88.

#### **COUNT VI: FRAUDULENT CONCEALMENT**

89. Merck repleads its answers to Paragraphs 1 through and including 88, and ANSWER TO COMPLAINT

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by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth verbatim.

- Merck denies each and every allegation of Paragraph 90, including each 90. and every allegation contained in subparts (a) through (b).
  - Merck denies each and every allegation of Paragraph 91. 91.
  - Merck denies each and every allegation of Paragraph 92. 92.
  - Merck denies each and every allegation of Paragraph 93. 93.
  - Merck denies each and every allegation of Paragraph 94. 94.
  - Merck denies each and every allegation of Paragraph 95. 95.
  - Merck denies each and every allegation of Paragraph 96. 96.

#### GLOBAL PRAYER FOR RELIEF

Merck denies that Plaintiff is entitled to any of the relief requested in his Global Prayer for Relief.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

#### **AFFIRMATIVE DEFENSES**

Discovery and investigation may reveal that any one or more of the following additional defenses should be available to Merck in this matter. Merck, therefore, asserts said additional defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these additional defenses as it may deem appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

#### FIRST AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

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#### SECOND AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

#### THIRD AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

#### FOURTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

#### FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

#### SIXTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

#### SEVENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were cause in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

#### EIGHTH AFFIRMATIVE DEFENSE

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by the application of the doctrine of comparative fault.

#### NINTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and

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willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

#### TENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

#### **ELEVENTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

#### TWELFTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

## THIRTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.

#### FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

#### FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

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#### SIXTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

#### SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

#### EIGHTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

#### NINETEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

#### TWENTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

#### TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under Section 4, et seq., of the Restatement (Third) of Torts: Products Liability.

## TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

## TWENTY-THIRD AFFIRMATIVE DEFENSE

There is no practical or technically feasible alternative design that would have ANSWER TO COMPLAINT 12

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reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

#### TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part by failure to mitigate damages.

#### TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

#### TWENTY-SIXTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recovery for strict liability because Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of action.

#### TWENTY-SEVENTH AFFIRMATIVE DEFENSE

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to unfair or deceptive practices are barred.

#### TWENTY-EIGHTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

#### TWENTY-NINTH AFFIRMATIVE DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the Constitution of the United States and the Constitution of California.

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#### **THIRTIETH AFFIRMATIVE DEFENSE**

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by this Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

#### THIRTY-FIRST AFFIRMATIVE DEFENSE

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

#### THIRTY-SECOND AFFIRMATIVE DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

#### THIRTY-THIRD AFFIRMATIVE DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

#### THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff has not sustained an ascertainable loss of property or money.

#### THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff has not suffered any actual injury or damages.

#### THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claimed are barred under the doctrine of economic loss.

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#### THIRTY-SEVENTH AFFIRMATIVE DEFENSE

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

#### THIRTY-EIGHTH AFFIRMATIVE DEFENSE

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

#### THIRTY-NINTH AFFIRMATIVE DEFENSE

This case is subject to dismissal or stay on the grounds of forum non conveniens.

#### FORTIETH AFFIRMATIVE DEFENSE

If Plaintiff have sustained injury or loss as alleged in the Complaint, such injury or loss may have been caused by parties other than answering defendant, or third persons not parties to this action, who may have been negligent, legally responsible, or otherwise at fault. In the event of a finding of liability in favor of Plaintiff, a settlement, or a judgment against answering defendant, answering defendant requests an apportionment of fault among all parties and third persons as permitted by Li v. Yellow Cab Company and America Motorcycle Association v. Superior Court. Answering defendant also requests a judgment and declaration of partial indemnification and contribution against all other parties or third persons in accordance with the apportionment of fault.

#### FORTY-FIRST AFFIRMATIVE DEFENSE

The asymptomatic plaintiff lacks standing because they have suffered no damages and no injury-in-fact.

#### FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims of fraud are not pleaded with the required particularity.

#### FORTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff cannot recover for the claims asserted because Plaintiff has failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiff.

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#### FORTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims for breach of warranty are barred because Plaintiff did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

#### FORTY-FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

#### PRAYER FOR RELIEF

WHEREFORE, Merck prays as follows:

- 1. That Plaintiff takes nothing by the Complaint;
- 2. That this action be dismissed with prejudice;
- 3. That Merck be awarded its costs of suit herein, and its attorney's fees to the extent provided for by statute or contract;
  - 4. For such other and further relief as the Court deems just and proper.

Dated: October 3, 2007

VENABLE LLP DOUGLAS C. EMHOFF JEFFREY M. TANZER

Infirey M. Tanzer

Attorneys for Defendant

Merck & Co., Inc.

#### **DEMAND FOR JURY TRIAL**

Merck demands a trial by jury as to all issues so triable.

Dated: October 3, 2007

**VENABLE LLP** DOUGLAS C. EMHOFF JEFFREY M. TANZER

Attorneys for Defendant

Merck & Co., Inc.

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#### PROOF OF SERVICE

Attorneys for Plaintiff

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I am employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is Venable LLP, 2049 Century Park East, Suite 2100, Los Angeles, California.

On October 3, 2007, I served the foregoing document(s) described as **DEFENDANT** MERCK & CO., INC.'S ANSWER TO COMPLAINT: DEMAND FOR JURY **TRIAL** on the interested parties in this action addressed as follows:

Clayeo C. Arnold

Clifford L. Carter

Kirk J. Wolden

CLAYEO C. ARNOLD, P.C.

608 University Avenue Sacramento, ČA 95825

- By placing true copies thereof enclosed in a sealed envelope(s) addressed as X stated above.
  - BY MAIL (CCP §1013(a)&(b)): I am readily familiar with the firm's practice of collection and processing correspondence for mailing with the U.S. Postal Service. Under that practice such envelope(s) is deposited with the U.S. postal service on the same day this declaration was executed, with postage thereon fully prepaid at 2049 Century Park East, Suite 2100, Los Angeles, California, in the ordinary course of business. ×
  - BY OVERNIGHT DELIVERY (CCP §1013(c)&(d)): I am readily familiar with the firm's practice of collection and processing items for delivery with Overnight Delivery. Under that practice such envelope(s) is deposited at a facility regularly maintained by Overnight Delivery or delivered to an authorized courier or driver authorized by Overnight Delivery to receive such envelope(s), on the same day this declaration was executed, with delivery fees fully provided for at 2049 Century Park East, Suite 2100, Los Angeles, California, in the ordinary course of business. П

Executed on October 3, 2007 at Los Angeles, California

- (STATE) I declare under penalty of perjury under the laws of the State of California that the above is true and correct.
- × (FEDERAL) I declare that I am employed in the office of a member of the Bar of this Court at whose direction the service was made. I declare under penalty of perjury under the laws of the United States of America that the above is true and correct.

Jesse Rodriguez

ANSWER TO COMPLAINT